

The Rt Hon Steve Barclay MP
Department of Health and Social Care
39 Victoria Street
London
SW1H 0EU

Sent via email to dhsc.sofs@dhsc.gov.uk

11 September 2023

Dear Secretary of State,

Subject: Marketing of laboratory tests direct to the public

Diagnostic tests are being marketed to the public in ways that create patient safety issues.

Currently, the diagnostics testing market lies outside the remit of the Medicines and Healthcare Regulatory Agency (MHRA) and the availability and use of these unregulated diagnostic tests and testing kits are a cause for concern.

While the use of self-testing kits for monitoring long term conditions is evidence-based and has our support, the unregulated marketing of diagnostic tests has detrimental effects on the targeted consumers, and other patients.

In our healthcare services, diagnostic tests and testing kits are selected, executed, and interpreted, by highly qualified and regulated professionals. This ensures safe, high-quality results that are interpreted and reported on correctly.

The main issues with an unregulated diagnostic testing market:

- **Capacity issues** within the NHS are enabling the exploitation of the ‘worried well’ – selling anxious people data without providing them with any professional support, and often no interpretation of their data. In turn, this often leads to further strain on capacity as the patient seeks support or interpretation.
- There is a **lack of evidence** regarding test development and patient instruction. For example, there is a danger that the tests are conducted without the quality assurance which is a hallmark of medical laboratory practice throughout the NHS and private healthcare (e.g. to ISO15189:2022 standards).
- The marketing strategy for some tests includes a **refund for normal results**. Incentivising abnormal results leads to unwarranted and unnecessary workload for both primary and secondary care because of the need for clinical confirmation.

We welcome improved patient access to diagnostic results using innovative technology. However, leaving the commercial sector of diagnostic testing unregulated harms healthcare services and the public.

We are now asking Government to supply appropriate support and regulation for this market.

We look forward to supporting you in delivering this.

Yours sincerely,



Debra Padgett FIBMS CSci
President
Institute of Biomedical Science



Professor Michael Osborn MRCS FRCPath
President
Royal College of Pathologists



Professor Kamila Hawthorne
Chair
Royal College of General Practitioners



Katherine Hayden FRCPath CSci EuSpLM BSc
President
Association for Clinical Biochemistry and
Laboratory Medicine